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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,286	12/03/2003	Herbert W. Harris	18184-0001 CI1	7923

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	**PAPER NUMBER**
1614	
MAIL DATE	**DELIVERY MODE**
05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,286	HARRIS ET AL.	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims and Examination

Claims 1-47 are pending and the subject of this Office Action.

Applicants' argument, filed on 18 September 2006, has been fully considered and it is deemed to be persuasive regarding the restriction requirement. As a result, the previous restriction requirement is hereby withdrawn.

Unfortunately, upon reconsideration of the pending claims, as presented, the following election requirement is newly applied.

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 38-47, drawn to a method of increasing the absolute neutrophil count in an individual, comprising administering to said individual an effective amount of at least one compound of formula I, classified in class 514, subclass 221.

II. Claims 14-22 and 34-35, drawn to a method of treating an individual afflicted with neutropenia with at least one compound of formula 1, classified in class 514, subclass 221.

III. Claims 23-33, drawn to a method of preventing neutropenia in an individual who is at risk of developing neutropenia, said method comprising administering to said individual an effective amount of at least one compound of formula I, classified in class 514, subclass 221.

IV. Claims 36 and 37, drawn to a method of preventing in an individual who is at risk of developing neutropenia, said method comprising administering to said individual a

combination of at least one compound of formula I and one or more additional agents, classified in class 514, subclass 221.

Inventions II and IV, as well as Inventions III and V, are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, the subcombination of formula I and one or more additional agent in Groups IV and V are separately usable, because a chemotherapeutic agent, for example, can be utilized in the treatment of a cancer which is not necessarily related to neutropenia, and therefore, has a separate utility. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions I, II (along with IV), and III (along with V) are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as

claimed are distinct inventions. The inventions are distinct, because while each involves the administration of an effective amount of a compound of formula I, they are directed to different patient populations, one population being predisposed to neutropenia and another, being afflicted with neutropenia, for example. A search for one population would not necessarily yield results for the other.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Specie Election

This application also `contains claims directed to the following patentably distinct species: variations of compounds of formula (1), as disclosed in claims 1-15, 23-24, 34-36, and 38-47.

MPEP §809.02(d) states "[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary." Here, the claims recited such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

The presented claims provide a variety of possibilities for R^1, R^2, R^4, and R^5. For hypothetical exemplification purposes only, if each of the variables above were each limited to 10 possible moieties there would be 10^5 possible species of compounds to be searched.

Further, as shown by the following classifications, a majority of the combinations encompassed by the present claims have acquired a separate status in the art. Notwithstanding that the classification of some of the active agents is co-extensive, all of the claimed compounds are patently distinct, and they fully capable of supporting separate patents.

For the above reasons, an election of a single disclosed species for examination purposes is deemed necessary and proper.

The applicant is required under 35 U.S.C. 121 to elect a single disclosed specific formula I species within the elected restriction group for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In addition to the above election requirement under 35 U.S.C. 121, if Applicant elects Group II, Applicant must tell whether the treatment is with or without added drug therapy over formula I and if it is with such added drug therapy, must pick a specific therapy drug or combination from claims 17 or 18 plus electing either a corresponding drug from claim 19, or a generic drug not cited in claim 19, but yet within a type cited in claims 17 or 18. Applicant must also specify whether the side effect is due to therapeutic radiation therapy or not. If Applicant elects Group III, Applicant must also specify the orgin of the risk of developing neutropenia (i.e. a forthcoming drug therapy, immunodeficiency, or a forthcoming exposure to ionizing radiation). If Applicant elects immunodeficiency, Applicant must specify whether it is caused by cancer or a virus. If Applicant elects Group IV or Group V, Applicant must elect an additional agent from the lists disclosed in claims 34 or 35 and claims 36 and 37 respectively. Currently, claims 1-5, 14, 23, 34, and 36 are generic in their respective groups.

The applicant is advised that a reply to this requirement must include an identification of the species that is elected in each group consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Applicant is advised that in order for the reply to this requirement to be complete, it must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the application. Any amendment of the inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 A.M. until 5:00 P.M. on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application is proceeding is assigned 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

29 April 2007
ARH

Ardin H. Marschel 4/30/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER